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MEMORANDUM

To: Members of the Independent Laboratory Advisory Committee (ILAC)

From: Medical Marijuana Program Staff, DPBH

Date: July 30, 2015

Re: Staff Report: Research from other states regarding regulation by weight vs. active

ingredient; and limitations on purchase of flower vs. edible products - ILAC agenda

item 7

Numerous topics were discussed at the July 1, 2015 ILAC meeting. Division of Public and Behavioral Health (Division) staff were asked to provide insight on the following laboratory testing issues. The following research results were gathered from a variety of internet sources. Some of these were official government sites, others were unofficial sources. The Division is therefore not able to confirm the currency or accuracy of all the information that appears in this report.

Colorado

New law restricts retailers from selling more than an ounce of flowers or its equivalent (once established by the state) in marijuana products – including concentrates – to Colorado residents, and from selling no more than a quarter-ounce of flowers or its equivalent in products to non-residents.

Manufacturers must package and label edible retail marijuana products by standardized requirements for three categories:

Category #1 – Single-Serving Edible Retail Marijuana Product

- Single unit for sale
- Containing 10mg or less of active THC
- Example: One, 10mg or less cookie, truffle, or gummie, etc.
- Example: Two, 5mg cookies, truffles, or gummies, etc.

• Example: Pouch of granola, popcorn, etc.

Category #2 - Single-Serving Edible Retail Marijuana Products

- More than one, packaging- and labeling-compliant Single-Serving Edible Retail Marijuana Product (SSERMP), placed in external packaging, as the unit for sale to the consumer
- Total amount of active THC in unit for sale cannot exceed 100mg
- Example: Blister pack of 10mg or less pills, lozenges, gummies, etc. where each blister is Child-Resistant
- Example: Cardboard box or cellophane bag of compliant SSERMPs

Category #3 – Multiple-Serving Edible Retail Marijuana Product

- Single unit for sale
- Containing more than 10mg active THC but no more than 100mg
- The product is not a bundle of individually packaged and compliant SSERMPs, but product has demarcations that allow it to be easily separated at each single serving of active THC
- Example: One, more than 10mg chocolate bar
- Example: One, more than 10mg soft drink
- Example: Child-Resistant Bottle of ten, 10mg or less pills / lozenges, Child-Resistant bag of ten, 10mg or less gummies or cookies, etc. not individually packaged
- Example: Five, 20mg cookies, where each cookie is demarcated down middle and each half is 10mg active THC

Washington

Labels for marijuana infused products (solid edible and liquid edible) must include a recommended serving size in total milligrams of active THC.

Illinois

IL law/regulations:

For purposes of labeling cannabis infused products, the pre-mixed total weight (in ounces or grams) of usable cannabis in the product is identified.

"Adequate supply" means:

2.5 ounces of usable cannabis during a period of 14 days and that is derived solely from an intrastate source

The pre-mixed weight of medical cannabis used in making a cannabis infused product shall apply toward the limit on the total amount of medical cannabis a registered qualifying patient may possess at any one time.

Maine

Dosage and form of marijuana. The registered patient shall let the facility know what dosage gives relief. The lowest dosage possible that gives the registered patient relief is optimal.

Registered patients may purchase no more than $2\frac{1}{2}$ ounces of prepared marijuana during a 15-day period and may possess no more than $2\frac{1}{2}$ ounces at any time.

Maryland

Definitions

"Medical marijuana-infused product" means oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical marijuana concentrate or usable marijuana that has been processed so that the dried leaves and flowers are integrated into other material. Only the weight of the medical marijuana-infused product that is attributable to marijuana shall count toward a 30-day supply.

"Usable marijuana" does not include seedlings, seeds, stems, stalks or roots of the plant or the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare a topical administration.

Packaging of Finished Medical Marijuana Product.

Must include a conspicuous itemization, including weight, of all cannabinoid and terpenoid ingredients specified for the product.

Licensed Dispensary Packaging and Labeling for Distribution Packaging Medical Marijuana for Distribution to a Qualifying Patient or Caregiver.

A licensed dispensary may only distribute medical marijuana in a package that shall: Must include a conspicuous itemization, including weight, of all cannabinoid and terpenoid ingredients specified for the product.

New Mexico

Maximum concentration of THC in concentrates: A licensed non-profit producer shall not sell or otherwise distribute a concentrated cannabis derived product to a qualified patient or primary caregiver that contains greater than seventy percent (70%) THC by weight, unless the qualified patient or primary caregiver presents proof of a valid medical exception granted by the department.

"Concentrated cannabis-derived product ("concentrate")" means a cannabis-derived product that is manufactured by a mechanical or chemical process that separates any cannabinoid from the cannabis plant, and that contains (or that is intended to contain at the time of sale or distribution) no less than thirty-percent (30%) THC by weight.

New York

Manufacturing requirements for approved medical marihuana products

A registered organization shall only produce such forms of medical marihuana as approved by the department according to the following requirements:

The final medical marihuana product shall not contain less than ninety-five percent (95%) or more than one hundred-five percent (105%) of the concentration of total THC or total CBD indicated on the label for this brand. Each brand shall have a maximum of 10mg total THC per dose.

The registered organization shall offer and make available to patients at least one brand that has a low THC and a high CBD content (e.g., a 1:20 ratio of THC to CBD).

Vermont

Dispensaries; conditions of operation

Weight of marijuana within marijuana infused products: Marijuana placed within the ingredients used in marijuana infused products shall be calculated by the amount or weight used within the ingredients. The amount of ingredients by weight including the amount marijuana extract used in the ingredients shall be calculated in each batch or container of marijuana infused products.

All products will be weighed, labeled, with ingredients including "gram weight equivalent" of marijuana extract used.

Only the portion of marijuana extract used within the ingredients shall count towards the possession limits of the dispensary and the patient.

Nevada

Question: Will the state consider the limit of 70 g. (i.e., 2.5 ounces per 14-day period) of concentrate the same as 70 g. of flower?

Answer: No.

Question: How will products of extractions be measured? By weight or by cannabinoid strength?

Answer: "Products of extraction" should be regulated and limited by a specified weight (milligrams) of THC per 14-day period.

NRS 453A.110 "Marijuana" defined. "Marijuana" has the meaning ascribed to it in NRS 453.096.

(Added to NRS by <u>2001</u>, <u>3055</u>)

SB447 recently made the following amendment to the definition of marijuana:

NRS 453.096 is hereby amended to read as follows: 453.096 1. "Marijuana" means: (a) All parts of any plant of the genus Cannabis, whether growing or not; (b) The seeds thereof; (c) The resin extracted from any part of the plant [;], including concentrated cannabis; and (d) Every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin.

NRS 453A.160 "Usable marijuana" defined.

- 1. "Usable marijuana" means:
- (a) The dried leaves and flowers of a plant of the genus *Cannabis*, and any mixture or preparation thereof, that are appropriate for the medical use of marijuana; and
- (b) The seeds of a plant of the genus Cannabis.
- 2. The term does not include the stalks and roots of the plant. (Added to NRS by 2001, 3055; A 2003, 1430)

NAC 453A.078 "Usable marijuana" defined. (NRS 453A.370) "Usable marijuana" has the meaning ascribed to it in NRS 453A.160. (Added to NAC by Div. of Pub. & Behavioral Health by R004-14, 3-28-2014, eff. 4-1-2014)

NAC 453A.704 Maximum allowable quantity of edible marijuana products and marijuana-infused products. (NRS 453A.370) For the purposes of subparagraph (3) of paragraph (b) of subsection 3 of NRS 453A.200, the maximum allowable quantity of edible marijuana products and marijuana-infused products is an amount that is equivalent to 2 1/2 ounces of usable marijuana. (Added to NAC by Div. of Pub. & Behavioral Health by R004-14, 3-28-2014, eff. 4-1-2014)

NRS 453A.360 Requirements concerning edible marijuana products and marijuana-infused products. Each medical marijuana dispensary and facility for the production of edible marijuana products or marijuana-infused products shall, in consultation with the Division, cooperate to ensure that all edible marijuana products and marijuana-infused products offered for sale:

- 1. Are labeled clearly and unambiguously as medical marijuana.
- 2. Are not presented in packaging that is appealing to children.
- 3. Are regulated and sold on the basis of the concentration of THC in the products and not by weight.

4. Are packaged and labeled in such a manner as to allow tracking by way of an inventory control system. (Added to NRS by 2013, 3714)

Rationale:

Carbon Dioxide or gas (i.e. butane, propane) **extraction** are processes that produce a product referred to as **concentrate** (oil). Screening dried leaves and flowers of marijuana is another **extraction** process that separates trichomes to produce concentrated products such as **hash** or **resin**. Slow-cooking marijuana with butter, yet another **extraction** process, produces a concentrated product as the lipophilic nature of cannabinoids causes them to separate and concentrate. There has been confusion over whether "mixtures and preparations thereof," from the definition of "usable marijuana," includes products of **extraction**. SB447 amendments to the definition of "marijuana" clarified this by adding resins extracted and concentrated cannabis to the definition (see above). Dried leaves and flower as well as the products of extraction are all "usable marijuana." As such, considering the disparity in potency, it does not make sense to regulate all "usable marijuana" by the 2.5 oz. per 14-day limit. NAC 453A.704 (above) infers that edible and marijuana-infused products may be mutually exclusive from dry marijuana and that an equivalence must be established. We suggest that the determining factor is the occurrence of **extraction** as has been described.

NRS 453A.360 (above) specifically states that edible and marijuana-infused products be regulated and sold on the basis of the concentration of THC in the products and not by weight. If one accepts that 1) THC is the primary "concern," and 2) that different types of raw material have different THC contents on a per-unit-weight basis (e.g., 2.5 oz. of flower is vastly different from 2.5 oz. of fan leaves), then it makes sense to think about equivalency from the standpoint of THC found in flower. An equivalence to our "usable marijuana" possession limit should be established as follows and measured by milligram of THC:

For Oils (Butane Hash Oil/CO₂), Extracts

Amount of Flower (grams) in 2.5 oz = 70.85 g

THC Calculator

THE CHICAGO	
Total Amount of Flower (oz.)	2.5
Grams of flower (g.)	70.85
Percent THC of Flower	15%
Grams of pure THC in Flower (g.)	
(70.85*15%)	10.6275
mg of Pure THC	
(10.6275*1000)	10627.5

Amount of BHO (grams) assuming 60% THC (Grams of pure THC in flower / 60% assuming extraction process yields 60% THC)(10.6275/60%)

% THC in BHO

60%

17.7125

Edible Calculator

mg THC per 14-day period	10627.5
Concentration of THC in edible (mg.)	
(assuming serving size will be 10 mg.)	10
Total number of edible servings allowed	
per 14 days (10627.5/10)	1062.75

^{*}tables above are from a spreadsheet where variables in yellow can be tweaked; however, appropriate ranges for % THC of flower to be used should be a primary point of discussion.

RECOMMENDATION

The Division policy should limit purchases of edibles and infused products (incorporating the **products** of extraction processes) to 10,000 mg. of THC per 14-day period. For those edibles that incorporate dried leaves and flowers that have not undergone extraction, the possession limit for "usable marijuana" (2.5 ounces of usable marijuana per 14-days) will remain intact via labeling of "marijuana weight (dry)." Recommended serving size is 10 milligrams of THC. Although the Division defines a serving size as 10 mg THC, each patient's appropriate amount is to be determined in consultation with his or her physician.

Nevada References

- Calculations in tables were provided by Jason Strull of 374 Labs
- Concepts focusing the equivalence of our statutory possession limits to milligrams of THC by Shane Johnson MD (NNV Service /Ops dba: Silver State Trading)
- Pritchard, Ry, and Browne, Jake. "The cannabis lexicon: Terms to know, from A-Z." *The Cannabist.* 13 June 2014. Web. 24 June 2015.